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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,561	12/08/2003	Sharad K. Govil	MTI 3.0-025 DIV DIV	4254

530 7590 07/21/2008

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EXAMINER	
SULLIVAN, DANIELLE D	

ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
07/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/730,561	GOVIL ET AL.	
	Examiner	Art Unit	
	DANIELLE SULLIVAN	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-67,69-76,78-111 and 113-119* is/are pending in the application.

4a) Of the above claim(s) *29-66* is/are withdrawn from consideration.

5)☒ Claim(s) *94-111 and 113-119* is/are allowed.

6)☒ Claim(s) *67,69-76 and 78-93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner for this application has changed from Edward Webman to Danielle Sullivan who can be contacted at 571-270-3285. Claims 1-28, 68, 77, 120 and 121 have been cancelled. Claims 29-66 have been withdrawn. Claims 67, 69-76, 78-119 are pending examination on the merits at this time.

Withdrawn rejections

Applicant's amendments and arguments filed 03/10/2008 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below are herein withdrawn. The terminal disclaimer filed on 3/10/2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of Patent No. 7,070,808 and 7,150,881 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 67, 69-76, 78-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miranda et al. (US 5,474,783).

Applicant's Invention

Applicant claims a transdermal delivery system comprising a blend of (a) one or more hydrophobic adhesive polymers; (b) a therapeutically effective amount of one or more drugs; and (c) a solvent system chosen from a solvent free of low volatility solvents or a solvent system consisting of a solvent that is volatile.

Applicant limits the drugs to being highly plasticized and includes selegiline, fluoxetine, tetracaine and chloropheniramine. Claims 72 and 83 limit the drugs to 3% to 35% of the composition. Claims 74, 75, 83 and 84 further specify that the drug is 3% to 18% selegiline. Regarding claims 72 and 81 the hydrophobic adhesive polymers comprise acrylic polymers.

Regarding claims 81, 85 and 91, Applicant further claims the invention as addressed above wherein (a) comprises one or more hydrophobic acrylic adhesive polymers and one or more secondary adhesive polymers. Claim 89 limits the adhesive to including 40-90% C4-C12 alkyl acrylates, between 10-40% C1-C3 alkyl acrylates hardening monomers. Claim 90 limits the system to including between 1-20% by weight of the monomer which provides functional groups for crosslinking. Claims 86, 87, 92 and 93 further limit the adhesive polymers to polyisobutylenes and silicones.

Determination of the scope and the content of the prior art

(MPEP 2141.01)

Miranda et al. teach a transdermal comprising a drug, an acrylate polymer and a poysiloxane (abstract). 2-96% polyacrylate and 98-4% polysiloxane (silicone) is disclosed (column 4, lines 10-12). The acrylate polymer is composed of at least 50% alkyl acrylate monomer, from 0-20% a functional monomer and 0 to 40% of other monomers (column 9, lines 38-42). Butyl acrylate is disclosed (column 9, line 44). The drug is 0.3-50% of the composition (column 8, line 67-column 9, line 2). Selegiline is disclosed (column 12, line 29). Ethanol (bp 78.5 C=168 F) is disclosed (column 15, line 14). In a preferred embodiment a dermal composition is prepared by mixing polyacrylate, the polysiloxane, drug, co-solvents and tackifying agents, *if needed in an appropriate volatile solvent* (column 15, lines 7-17). Cosolvents include alcohols and propylene glycol (column 13, lines 48-50).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Miranda et al. do not teach a solvent system chosen from a solvent free of low volatility solvents or a solvent system consisting of a solvent that is volatile. However, Miranda et al. teach the use of cosolvents including alcohols, such as ethanol and glycol. Optionally, additional solvents may or may not be added depending on the drug used.

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to make a composition comprising a solvent system chosen from a solvent free of low volatility solvents or a solvent system consisting of a solvent that is volatile in view of Miranda et al. One would have been motivated to include a solvent system chosen from a solvent free of low volatility solvents or a solvent system consisting of a solvent that is volatile because Miranda et al. teaches that the composition is prepared by mixing cosolvents, which may be volatile or have low volatility and if necessary volatile solvents in order to deliver a drug transdermally. Furthermore, Miranda et al. teach that the volatile solvents are optional, and therefore read on compositions free of low volatility solvents.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 76, 79-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolter et al. (US 5,462,746).

Applicant's Invention

Applicant claims a transdermal delivery system comprising a blend of (a) one or more hydrophobic adhesive polymers; (b) a therapeutically effective amount of one or more drugs; and (c) a solvent system consisting of a solvent that is volatile.

Claim 79 and 80 limit the drugs to being highly plasticized and includes selegiline, fluoxetine, tetracaine and chloropheniramine. Claim 82 limit the drugs to 3% to 35% of the composition. Claims 83 and 84 further specify that the drug is 3% to 18% selegiline. Regarding claim 81 the hydrophobic adhesive polymers comprise acrylic polymers.

Regarding claim 81 Applicant further claims the invention as addressed above wherein (a) comprises one or more hydrophobic acrylic adhesive polymers and one or more secondary adhesive polymers.

Determination of the scope and the content of the prior art

(MPEP 2141.01)

Wolter et al. teach a transdermal comprising an adhesive, a drug or salt thereof, and, when the salt is present, an element containing basic groups (abstract). Deprenyl (selegeline) is disclosed (column 3 line 44). Ethyl acetate (bp 77° C=172° F) is specified as a solvent which evaporates (column 4 line 64). DURO-TAK 2516 [disclosed in applicants' specification in Table III as an acrylate polymer comprising ethylhexyl acrylate and methyl acrylate, crosslinked with aluminum] is specified (column 5 line 9).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Wolter et al. does not teach a solvent system consisting essentially of a solvent that is volatile. However, the use of ethyl acetate is disclosed. Additional solvents may or may not be added depending on the drug used.

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill to make a composition comprising a solvent consisting essentially of a solvent that is volatile in view of Wolter et al. One would have been motivated to include a solvent system chosen from a solvent that is volatile because Wolter et al. teaches that ethyl acetate evaporates. Absent a showing of criticality, optimum suitable amounts may be obtained by routine experimentation.

Response to Arguments

Applicant's arguments filed 03/10/2008 have been fully considered but they are not persuasive.

Applicant argues that Miranda et al. does not teach or suggest the present invention, especially in view of the solvent system required by the claims. The Examiner disagrees with this argument. Miranda et al. teach the absence of solvents which are of high or low volatility; see column 15, lines 7-17. Therefore, Miranda et al. is still applicable.

Allowable Subject Matter

Claims 94-111 and 113-119 are allowed.

The following is a statement of reasons for the indication of allowable subject matter: The terminal disclaimer filed on 3/10/2008 has obviated the rejection of the claims over Patent No. 7,070,808 and 7,150,881.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danielle Sullivan whose telephone number is (571) 270-3285. The examiner can normally be reached on 7:30 AM - 5:00 PM Mon-Thur EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Danielle Sullivan

Patent Examiner
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/Johann R. Richter/
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